K123995

PHILIPS

FEB 0 1 2013

510(k) Summary (21 CFR 807.92)

A. SUBMITTER INFORMATION

Submitter's name	Philips Digital Mammography Sweden AB
Address	Smidesvägen 5 SE-171 41 Solna Sweden
Establishment registration number	3009307584
Contact person	Mr. Gustav Lins
Telephone	+46-8-623 52 00
FAX	+46-8-623 52 01
Title	Manager Regulatory Affairs
Date of the summary preparation	2012-12-21

B. DEVICE IDENTIFICATION

Device trade name	MicroDose SI (model L50)
Device common name	Full-Field Digital Mammography X-ray System
Classification name	Full-Field Digital Mammography X-ray System
Classification product code	MUE
Device class	II
Regulation code	21 CFR 892.1715

C. DEVICE DESCRIPTION

The MicroDose SI (model L50) is a full-field digital mammography system comprised of an image acquisition system, a gantry and an acquisition workstation computer equipped with a keyboard, a keypad, a mouse, and a monitor. The image acquisition system includes a digital detector of photon counting technology, x-ray tube (with tungsten target and aluminum filtration), high voltage generator, compression paddle(s), and multi-slit collimator. The acquisition workstation is the user interface for preparing and initiating image acquisition, image processing, and image transfer to the desired destination (e.g. PACS) for diagnosis and archiving.

The MicroDose SI (model L50) detector is based on photon counting technology and consists of a large number of crystalline silicon strip detectors. The technology enables high detection efficiency of photons and efficient rejection of electronic noise. The MicroDose SI (model L50) uses a multi-slit scanning technique that prevents image degradation caused by scattered radiation by removing photons scattered in the breast and not directed towards the detector. These factors combine into a dose efficient system.
The MicroDose SI (model L50) provides three exposure modes; manual, automatic (parameters predefined based on compressed breast thickness), and SmartAEC. SmartAEC

continuously adjusts the exposure based on measured transmission from the leading detector edge.

The changes compared to the L30 model involves a minor modification to the collimator, such that the range of breast thickness that can be imaged on the device is slightly expanded.

D. INDICATIONS FOR USE

The MicroDose SI (model L50) is indicated for generating mammographic images that can be used for screening and diagnosis of breast cancer. The MicroDose SI (model L50) is intended to be used in the same clinical applications as traditional film/screen systems.

E. PREDICATE DEVICE

	Predicate device
Device Classification Name	Full Field Digital, System, X-ray, Mammographic
510(k) Number	K110025, K120255
Device Name	Philips MicroDose
Model	L30
Applicant	Philips Digital Mammography Sweden AB
Product Code	MUE
Advisory Committee	Radiology

F. TECHNICAL CHARACTERISTICS

The technical characteristics of the predicate device, the Philips MicroDose L30 have been described in two separate 510(k) submissions. The K110025 is the original application that cleared the device itself; the K120255 was used to gain FDA approval for the quantitative reduced dose claim for the MicroDose system. The basic fundamental technology which is described in these applications remains the same for the MicroDose SI (model L50).

In summary, the L30 and L50 models are based on the same photon counting detector technology, characterized by the absence of electronic noise. The configuration of silicon strip detectors for converting the X-ray quanta to electrical pulses is identical for the two models and there are merely slight modifications to the pulse counting electronics

G. CONCLUSION

The MicroDose SI (model L50) is based on the same fundamental technology as the predicate L30 model and there is no change in intended use. The equivalence in performance is supported through the performed verification and validation activities. The modifications to the device that are the subject of this 510(k) submission are minor in nature and are well characterized by the design control process and the physical laboratory test results showing the comparative performance of the modified device to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 1, 2013

Phillips Digital Mammogramography
C/O Gustav Lins
Manager Regulatory Affairs
SOLNA SE-171 41
SMIDESVAGEN 5
SWEDEN

Re: K123995
Trade/Device Name: Microdose SI (Model L50)
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: II
Product Code: MUE
Dated: December 21, 2012
Received: December 26, 2012

Dear Mr. Lins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sean M. Boyd -S for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: MicroDose SI (model L50)

Indications for Use: The MicroDose SI (model L50) is indicated for generating mammographic images that can be used for screening and diagnosis of breast cancer.
The MicroDose SI (model L50) is intended to be used in the same clinical applications as traditional film/screen systems.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Sean M. Boyd -S

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123995